



Specification of Final Product Hello Baby Plus

Criteria	Technical specification																																																								
Analytical Sensitivity (Limit of Detection)	15 mIU/mL of hCG																																																								
Analytical specification	<p>Cross-reactivity</p> <p>HelloBabyPlus” did not showed cross-reactivity with LH, FSH, TSH hormones</p> <table border="1"> <thead> <tr> <th>Homologous hormones</th> <th>Source</th> <th>Code No.</th> <th>Concentration tested</th> </tr> </thead> <tbody> <tr> <td>LH</td> <td>NIBSC</td> <td>3rd IS (81/535)</td> <td>500mIU/mL</td> </tr> <tr> <td>FSH</td> <td>NIBSC</td> <td>1st IS (92/512)</td> <td>1000mIU/mL</td> </tr> <tr> <td>TSH</td> <td>NIBSC</td> <td>1st IS (81/565)</td> <td>1000 μ IU/mL</td> </tr> </tbody> </table> <p>Interference</p> <p>18 interfering substances tested did not affect the performance of Hello Baby Plus</p> <table border="1"> <thead> <tr> <th>Analytes</th> <th>Concentration tested</th> <th>Analytes</th> <th>Concentration tested</th> </tr> </thead> <tbody> <tr> <td>Acetaminophen</td> <td>100 mg/dL</td> <td>Oxalic acid</td> <td>60 mg/dL</td> </tr> <tr> <td>Amoxicillin</td> <td>1,000 mg/dL</td> <td>Pyridoxine HCl</td> <td>10 mg/dL</td> </tr> <tr> <td>Ampicillin</td> <td>1,000 mg/dL</td> <td>Riboflavin</td> <td>60 mg/dL</td> </tr> <tr> <td>Ascorbic acid</td> <td>521 mg/dL</td> <td>Salicylic acid</td> <td>1,000 mg/dL</td> </tr> <tr> <td>Calcium pantothenate</td> <td>50 mg/dL</td> <td>Sodium chloride</td> <td>6,800 mg/dL</td> </tr> <tr> <td>Cyanocobalamin</td> <td>1 mg/dL</td> <td>Caffeine</td> <td>20 mg/dL</td> </tr> <tr> <td>Ethanol</td> <td>20 mg/dL</td> <td>Albumin</td> <td>20 mg/dL</td> </tr> <tr> <td>Glucose</td> <td>2,000 mg/dL</td> <td>Bilirubin</td> <td>20 mg/dL</td> </tr> <tr> <td>Nicotinic acid amide</td> <td>250 mg/dL</td> <td>Hemoglobin</td> <td>1,000 mg/dL</td> </tr> </tbody> </table>	Homologous hormones	Source	Code No.	Concentration tested	LH	NIBSC	3 rd IS (81/535)	500mIU/mL	FSH	NIBSC	1 st IS (92/512)	1000mIU/mL	TSH	NIBSC	1 st IS (81/565)	1000 μ IU/mL	Analytes	Concentration tested	Analytes	Concentration tested	Acetaminophen	100 mg/dL	Oxalic acid	60 mg/dL	Amoxicillin	1,000 mg/dL	Pyridoxine HCl	10 mg/dL	Ampicillin	1,000 mg/dL	Riboflavin	60 mg/dL	Ascorbic acid	521 mg/dL	Salicylic acid	1,000 mg/dL	Calcium pantothenate	50 mg/dL	Sodium chloride	6,800 mg/dL	Cyanocobalamin	1 mg/dL	Caffeine	20 mg/dL	Ethanol	20 mg/dL	Albumin	20 mg/dL	Glucose	2,000 mg/dL	Bilirubin	20 mg/dL	Nicotinic acid amide	250 mg/dL	Hemoglobin	1,000 mg/dL
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Precision	100%																																																								
Reading time	3 minutes																																																								

QMR: *10/2 6/1/13*

Park, Hye Lim

Date: *2022/11/07*